



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

24 November 2017

FRANCISCO T. DUQUE III, MD, MSc

Secretary

Department of Health

Dear **Secretary Duque**:

The Formulary Executive Council (FEC) respectfully recommends the **DISAPPROVAL** of the inclusion of **insulin glulisine 100 IU/mL, 10 mL vial and 3 mL pre-filled pen** in the Philippine National Formulary (PNF) because after careful appraisal and deliberation, it was noted that most of the studies (i.e., eight out of nine) submitted by the drug manufacturer did not satisfy the inclusion criteria for articles based on the research question set by the Council, either because the comparator used is not human insulin or the studies are not phase II or III randomized controlled trials. As such, these cannot be used to update the evidence review which served as the basis of the previous FEC recommendation for disapproval. Meanwhile, the only study which satisfied the criteria has a small sample size and therefore is unlikely to change the estimates of the previous evaluation which showed that even though insulin glulisine has slight advantage compared to regular insulin in terms of reduction in HbA1c, this is considerably small and may not be clinically significant. In terms of cost, insulin glulisine is also more expensive than regular insulin by around 20%. Given these, the Council's recommendation to disapprove the inclusion of insulin glulisine still remains.

Please be informed that the above recommendation was posted on the website of the Pharmaceutical Division to accommodate any comment or appeal from the involved stakeholders within 30 days.

For your disposition, Sir.

Thank you and best regards.

Very truly yours,

For the Formulary Executive Council


A handwritten signature in black ink, reading "Froilan A. Bagabaldo".

ATTY. FROILAN BAGABALDO

Chair

Formulary Executive Council

Recommending disapproval:


ENRIQUE A. TAXAG, MD, PPSAE, FPSMID, CESO III
OIC – Assistant Secretary of Health
Office for Policy and Health Systems

Official disapproval of the above medicine:


FRANCISCO T. DUQUE III, MD, MSc
Secretary